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(54) Title: PAIN RELIEVER AND METHOD OF USE

(57) Abstract: A composition containing capsicum extract together with other ingredients to neutralize the discomfort resulting from the application of capsicum extract to the skin enabling treatment of many types of discomforts, including arthritis pain, neuropathy, post surgical scarring, hemorrhoid pain and itching, and pruritis without the discomfort normally associated with the topical application of capsicum extract.

PAIN RELIEVER AND METHOD OF USE

BACKGROUND OF THE INVENTION

The present application claims priority to co-pending application Serial No. 09/662,962 filed September 15, 2000; and to co-pending application 09/800,245 filed March 6, 2001, both of which are continuation-in-part applications based on application Serial No. 09/408,740 filed September, 29,1999, now U.S. Letters Patent No. 6.197,823.

Arthritis is a common chronic problem, which occurs below the surface of the skin. Millions of people and animal have the condition. Various topical creams and ointments are sold for treatment of arthritis; however, most utilize an anesthetic, such as lidocaine, benzocaine or other numbing agent for the skin surface.

Several topical agents (creams, ointments, liniments and the like) have been utilized for the relief of the pains and aches of arthritis. Most of these have provided a little, but only temporary, relief to persons suffering from pain. Many combinations of varying ointments, creams, aqueous solutions, liniments and the like for the treatment of arthritis are known. The most efficacious of these contains as its active ingredient the vegetable products derived from the seed and pods of the capsicum plant, commonly known as red pepper. Capsicum-derived ointment is devised for external application to the affected area of the body by applying to the area adjacent to the muscle, joint or tendon and rubbing it into the skin. The active ingredient is capsaicin. With initial as well as persistent application, capsaicin is effective to relieve the aches and pains of various muscle or skeletal origin, such as arthritis, muscle strains, tendinitis, bursitis and soft tissue diseases.

Capsaicin is also effective to relieve the various musculoskeletal pains, itching, neuropathic pains, dysesthesias caused by shingles, post herpetic neuralgia, post mastectomy pain, and peripheral neuropathies. It is further commonly prescribed to reduce the pain of neuropathies produced by diabetes (burning pain, discomfort, often at night) and other diseases that are neuropathic in origin including the discomfort and odd sensations of shingles (post herpetic neuralgia, which can be extremely painful), as well as dysesthesias that can occur with thoracotomies and post surgical scars.

Unfortunately, although capsaicin is often the most effective agent available, the active ingredient is a potent skin irritant, producing a burning, uncomfortable sensation to the skin. Although prescribed frequently, it is used to only a limited extent due to this unpleasant side effect.

The burning side effect has also discouraged the use of capsaicin to treat other types of

discomfort, such as pruritus or itching. Pruritus or itching can be caused by many stimuli, such as poison ivy, hemorrhoids, or athlete's foot. The unpleasant side effects of capsaicin have discouraged its use to treat such types of discomfort. Also, the burning that occurs when the skin is exposed to sunlight that has been treated with capsaicin or exposed to water has discouraged the use of capsaicin.

A capsaicin based pain reliever which does not irritate the skin or cause a burning discomfort even when exposed to water and sunlight, would be extremely desirable and acceptable to patients and people in general who are experiencing the types of pain or discomfort outlined above.

Prior attempts to produce such an invention can be seen in U.S. Patent No. 5,134,166 and U.S. Patent No. 4,997,853 that use anesthetics in association with capsaicin, effectively numbing sites. The present invention does not attempt to numb the site, and instead permit continued use of a hand or foot, with sensory input, rather than simply stopping all sensory input to the area while warming with capsaicin.

The present invention was developed to provide a lotion, which has as the three critical ingredients, capsaicin, plus an anesthetic and an analgesic. The composition overcomes other obstacles of known capsaicin creams in that the amounts used enable the warming relief of the peppers in combination with the coolness of the anaesthetic, yet enable the user to still feel objects they touch due to the use of an analgesic as a critical component rather than large amounts of analgesics.

Various capsaicin compositions have been developed over the years, in particular, the psoriatic cream of U.S. Patent 4,486,450, the nasal composition of U.S. Patent 5,134,166, and the cream of U.S. patent 4,997,853, the anti-inflammatory composition of U.S. Patent 5,560,910, the composition of U.S. Patent 5,962,532, the composition for animals of U.S. Patent 5,916,565, the stomach treatments of U.S. Patent 5,889,041, the composition of U.S. Patent 5,827,886, the patch with medication of U.S. Patent 5,741,510, all of which are incorporated by reference herein.

After many years of research and testing on subject, the present invention has been developed which does not rely on topical anesthetics, such as lidocaine (Entry 5310, p. 786 Merck Index, Tenth Edition 1983) and benzocaine (ethyl aminobenzoate, Entry 3710, p. 546 Merck Index, Tenth Edition, 1983) into formulations containing capsaicin, and then applying such formulations for the initial period of treatment to eliminate the painful burning from the application of capsaicin, allowing the patient to continue therapy while being able to feel through the skin onto which the lotion is applied.

Arthritis is a common chronic problem, which occurs below the surface of the skin. Millions of people and animal have the condition. Various topical creams and ointments are sold for treatment of arthritis; however, most utilize an anesthetic, such as lidocaine, benzocaine or other numbing agent for the skin surface.

OBJECTS OF THE INVENTION

It is an object of this invention to provide a capsaicin based pain reliever that does not burn when applied topically, or when exposed to sunlight or water.

It is another object of this invention to provide a method for formulating a no-burn capsaicin-based pain reliever that relieves pain and discomfort and in which the capsaicin is fully functional, one that provides analgesic and anesthetic properties.

It is a further object of this invention to provide a method for treating pain and discomfort with capsaicin that does not burn the skin when applied topically or when exposed to sunlight or water.

SUMMARY OF THE INVENTION

The present invention relates to a method of treating arthritis using a lotion composition therefore in which capsaicin is used as the principle therapeutic agent along with an analgesic and an anaesthetic in a lotion.

An object of the present invention is to provide a lotion, which is easily applied, easy to absorb into the skin, and provides ability to feel objects.

In accordance with one aspect of the invention, there is provided a composition comprising a carrier, capsaicin, an encapsulation agent, an ester of amino acid and a light-diffusing compound.

In accordance with another aspect of the invention, there is provided a method for treating a victim of pain or discomfort. The treatment comprises applying the above-described composition topically to the skin of the victim near an area affected by the pain or discomfort.

In accordance with a further aspect of the invention, there is provided a method for making a composition useful for topical application to treat pain or discomfort. The method is carried out by mixing a carrier to form an aqueous solution, adding an encapsulation agent to reduce burning of the capsaicin, adding an amount of esters of amino acids and finally adding a light refractive element having an ability to stop secondary burning effect by the capsaicin due to the suns rays. The resulting aqueous solution preferably has a cream-like viscosity.

DETAILED DESCRIPTION

Capsaicin is trans-8-methyl-N-vanillyl-5 nonenamide, a naturally occurring alkyl vanillylamide, a type of capsaicinoid. It is found in high concentration in fruit of plants of the Capsicum genus. The genus capsicum is a member of a large tropical family Solanaceae. There are numerous species, of which Capsicum annum, Capsicum chinese and Capsicum frutescens are closely related. Capsicum frutescens is also known as Cayenne Pepper, Chili Pepper, Pimento Tabasco Pepper and Tabasco-sauce pepper. The chili pepper, red pepper and paprika all are species of Capsicum. All hot peppers contain capsaicinoids. Capsaicinoids are natural materials, which produce a burning sensation in the mouth. Capsicum has recently been officially defined in the US Pharmacopia 23 where it is defined as the dried ripe fruit of Capsicum frutescens Linne or Capsicum annum Linne.

There are two main capsaicinoids, capsaicin and dihydrocapsaicin and three minor capsaicinoids, nordihydrocapsaicin, homocapsaicin and homodihydrocapsaicin. All capsaicinoids are considered usable within the scope of this invention.

Capsicum is the dry powder obtained by grinding up the fruits of these plants. Capsicum oleoresin (or capsaicin oleoresin) is the liquid concentrate extracted from the dry powder. Capsaicin, a white crystalline material, is obtained from the liquid concentrate.

Capsaicin (N-Vanillyl-8-methyl-6-(E)-noneamide) is the most pungent of the capsaicinoids. It is very soluble in fats, oils and alcohols. Capsicum also contains a red coloring matter, oleic acid, palmitic acid and stearic acid. Capsicum frutescens extract can be obtained from Bio-Botanica, Inc. of Hauppauge, New York and appears as a viscous fluid, having a sallow yellow color, a caustic and pungent aroma, and is soluble in ethanol. Capsicum is a powerful local stimulant. It is strongly rubefacient acting without vesication.

The lotion of the invention comprises capsaicin as a first active ingredient. Generally speaking, the lotion will contain in the range of about 0.00125% to about 1.0% by weight of capsaicin. Compositions containing more than about 1.0% by weight of capsaicin will provide a therapeutic effect, with up to 62.0% by weight capsaicin, except that the burning side effect will increase in proportion to the increase percentage of capsaicin. Compositions containing 0.025% to 20.0% by weight of capsaicin could be used. Compositions of 0.025 to 2.0% by weight are considered usable as well.

Compositions containing in the range of 0.025% to 0.25% by weight of capsaicin are preferred because they are narrowly encompassed within current FDA guidelines regarding capsaicin use. However, the FDA guidelines were developed at a time when there was not an

effective method for relieving the discomfort generated by capsaicin. The present invention provides a method to increase the amount of capsaicin that can be administered comfortably.

In the present invention, capsaicin is mixed with a carrier fluid. Preferably, the carrier fluid is water-based and forms an aqueous solution containing the ingredients. However, the carrier may be a fluid, such as an oil based carrier, a fat based carrier, a fatty alcohol based carrier or a combination of these carriers. Deionized water also can be used as the carrier for the present invention.

The composition also may comprise an analgesic as a second active ingredient. Additional irritant can be added to the capsaicin and carrier. Histidines, such as a histamine dihydrochloride, are considered usable in the scope of the present invention to create vasodilation, and act as a second irritant. It is possible to add more than one histidine to achieve the analgesic reaction. Thus, any one of the following histidines, or combinations thereof, are considered usable in this invention: L-histidines, histamine dihydrochloride, DL-histidine, D-histidine hydrochloride monohydrate, L-histidine hydrochloride monohydrate, L-histidine methyl ester dihydrochloride, L-histidinol dihydrochloride, histamine phosphate.

Adding the second irritant produces an analgesic effect and does not numb the site, like an anesthetic or depress cutaneous sensory receptors. Instead, it has a topical counter-irritant effect by stimulating cutaneous sensory receptors, see, Federal Register, Vol. 48, No. 27, Tuesday February 8, 1983, pages 5367 et. seq. Specifically, amine and caine type local anesthetics, such as benzocaine and lidocaine, act differently as anesthetics not producing an analgesic effect which is achieved by adding an additional irritant, such as a histamine hydrochloride or most preferably a histamine dihydrochloride. If a histamine dihydrochloride is used, it is preferred to use a starting composition of 98% histamine, although compositions in the range of 96-99% histamine will be usable as well.

The novel lotion of the present invention also uses an encapsulation agent, suitable examples of which include colloidal oatmeal, hydrogenated lecithin, dipotassium glycyrrhizinate. Similar encapsulation agents, or even combinations of these agents, have been found to be effective. Preferably, the encapsulation agent is colloidal oatmeal. The colloidal oatmeal has intrinsic SFP, natural sunscreen capability. In addition, the colloidal oatmeal encapsulates the capsaicin to reduce the inflammation effect the capsaicin has on the skin, while still enabling the capsaicin to work effectively. Typically, up to about 3.0 wt. % colloidal oatmeal is used in this invention, although any amount between about 2.0 wt. % and up to about 10.0 wt. % can be used. The colloidal oatmeal works within the scope of this invention because it contains hydrophilic colloids. These colloids

help to provide a protective barrier on the skin to control inflammation. In addition, histidines, such as L-histidines, are present in colloid oatmeal. Histidines can be present in the oats in weight percents of up to about 3.0% of the total amino acids in the oats. The invention has found that using the colloidal oats synergistically enhance the histamine dichlorohydride effect, when histamine dichlorohydride is used.

The unique formulation is a topically (externally) applied formulation which has three simultaneous effects, analgesic, anesthetic and antipruritic effects, by (1) depressing cutaneous sensory receptors to relieve pain and (2) stimulating cutaneous sensory receptors using a topical counter irritant. It is the combination of analgesic and anesthetic effects, which make this invention unique.

The composition of the present invention also may comprise other additives. For example, the lotion may contain a coagulating agent, suitable examples of which include xanthum gum, myristal myristate, polyethylene glycols (PEG's) and other stearates for coagulation of the compound.

The composition also may comprise a transdermal activator. "Lavender flower oil" or lavender oil, and a "bergaptene-free" bergamot oil or bergamot extract can be beneficial in that the lavender is an active transdermal activator which causes the formula to penetrate the skin; rather than remaining on the surface of the skin. Lavender oil and bergamot extract also are beneficial in that both provide muscle relaxant characteristics. The bergamot oil also provides help with acne, fevers, herpes, and diabetic neuropathy. Between about 1.0 and 2.0 wt. % of lavender oil is needed for transdermal activation, but between about 0.5 and about 5.0 wt % can be used.

The composition also may comprise a suspension agent. A suitable example of a suspension agent is alkyl benzoate. Alkyl benzoate is considered usable within the scope of the present invention, and helps to suspend the particle size of the colloidal oatmeal and titanium dioxide.

The lotion also can include any of the following components: Arnica montana, Hypericum perforatum (known as St. John's Wort), Aloe barbadensis gel, Citric acid to adjust the pH of the compound, amino acid esters such as lauryl menthyl esters, propylene glycol with methyl and propyl parabens as preservatives, a chelating agent to keep the product from separating, such as edetatedisodium, triethanolamine hydrochloride which acts as a reagent, other preservatives and Benzoin derivatives.

Still other components considered usable in the present invention are phenoxy ethanol, ethyl paraben, and butyl paraben as preservatives, or in the preservative system. Other ingredients, such as inositol, methyl paraben, propyl paraben, hydroxy ethyl cellulose can be used therein, for

formulations which are gels rather than creams. Carbomer 940 can be used to make the formula into a gel rather than a cream.

The present invention also may comprise menthol or an ester of an amino acid from which menthol can be obtained. The addition of menthol to the lotion of the present invention will provide the lotion with fast acting and long acting effects. Suitable esters of amino acids include for example menthyl and lauryl esters of amino acids and combinations thereof. A preferred ester of amino acid is menthyl lauryl pidolate.

The uses of the invention are contemplated for post perpetic neuralgia, and scar conditions after surgery, such as for treating the scars from a mastectomy. Also, the present invention is considered usably for victims of neuropathy, such as diabetes with neuropathy.

In the method of the invention, a victim of pain or discomfort is treated by applying the above-described composition topically to the skin of the victim near an area affected by the pain or discomfort. The types of pain or discomfort to which the invention may be applied include those discussed in the background of the invention. Generally speaking, the inventive composition is applied to the selected area, such as a joint, and rubbed in. The amount of lotion applied is not critical. Generally, it should be applied in an amount, which is sufficient to wet the area of application. Usually, the amount used will be in the range of from about 0.3 to about 3.0 ccs.

For the treatment of pruritus or itching, the application of the composition can be repeated as required to control the discomfort. When the preferred composition of the invention is applied, it provides near immediate relief from the itching caused by poison ivy or hemorrhoids, without a burning sensation. The relief lasts for several hours. It is surprising that a capsaicin-based composition would be useful for the treatment of such discomfort. To enhance the antipruritic effect, additional compounds can be added to the formulation. These components can be methyl sulphonyl methane, sodium bicarbonate, calamine, allantoin, kaolin, and combinations thereof.

For best results in the treatment of arthritis, the treatment should be repeated several times per day, such as in the range of 2 to 8 times per day, preferably 3-5 times per day, and continued for several days. Surprisingly, most patients do not experience the burning discomfort heretofore known as a very common side effect of topical capsaicin application.

It is contemplated to be within the scope of the present invention to use this formulation also as a spray using propellants, such as butyl propellants.

It is even contemplated that the present invention could be used as a patch for treatment as well. Propellant for the spray on composition contemplated as usable herein can be selected from the group butane, propane, isobutane, and combinations thereof. A foam version of the formulation,

additionally using a propellant and a surfactant is considered within the scope of the present invention. A preferred surfactant is a member of the group of amine oxides. The most preferred surfactant is alkyl dimethyl amine oxide.

In the present invention, capsaicin is distributed according to known techniques in various pharmaceutically acceptable carriers to form a lotion. Some of these carriers contain volatile diluents such as alcohol and may contain various emulsifying and suspending agents.

The present invention also may involve the use of an analgesic and an anesthetic in combination to produce a warm sensation on the patient's skin without the usual burning side effects of traditional capsaicin ointments or gels.

The invention also applies to a method for making the lotion comprising, the steps of mixing the preferred ingredients, heating the mixture to 60°C., adding the acetyl alcohol, the glycerol monostearate, the myristal myristate, the polysorbates and the titanium dioxide, then, one at a time, adding to the heated materials, benzyl alcohol, colloidal oatmeal, and lavender oil. While maintaining the temperature, the xanthum gum is dissolved into the propylene glycol, water and Uniphen P-23. The blended ingredients should then be removed from heat and the capsaicin should be dissolved into the benzyl alcohol the mixture is cooled to 40°C., the capsaicin is blended into the mixture forming the lotion.

The forgoing is a description of the composition and method of use of three embodiments of the invention. The scope of the invention is considered to include the described embodiment together with others obvious to those skilled in the art. It should be understood that the foregoing relates only to a preferred embodiment of the present invention and that numerous modifications or alterations may be made therein without departing from the spirit and scope of the invention as set forth in the appended claims.

In one aspect, this invention relates to a composition of matter useful for treating bodily pains and discomforts. In another aspect, this invention relates to a method for treating bodily pains and discomforts. In yet another aspect, this invention relates to formulating a pain and discomfort reliever.

There are two main capsaicinoids, capsaicin and dihydrocapsaicin and three minor capsaicinoids, nordihydrocapsaicin, homocapsaicin and homodihydrocapsaicin. All capsaicinoids are considered usable within the scope of this invention.

The composition of the invention comprises capsaicin as a first active ingredient and at least one second active ingredient acting as an analgesic to reduce the sensation of capsaicin induced skin irritation. The ingredients are contained in a carrier fluid. The genus capsicum is a member of a

large tropical family Solanaceae. There are numerous species, of which Capsicum annum, Capsicum chinese and Capsicum frutescens are closely related. Capsicum frutescens is also known as Cayenne Pepper, Chili Pepper, Pimento Tabasco Pepper and Tabasco-sauce pepper.

Capsicum is a powerful local stimulant. It is strongly rubefacient acting without vesication.

The dipotassium glycyrrhizinate is prepared from finely cut licorice root extracted with water. Ethanol is then added to this extract and the precipitate is separated after sedimentation. Inorganic acid is added to the filtrate, and the precipitating sediment is filtered. After neutralization with water, it is dissolved in a potassium hydroxide solution and evaporated until dry. The residue is recrystallized in media such as acetic acid or ethanol to obtain monopotassium glycyrrhizinate. The product is faintly yellow without an order and sweet in taste. Typically this product can be acquired from Barnet Products Corp. of Englewood Cliffs, New Jersey.

Hydrogenated lecithin is available from Barnet Products Corporation, as well. It is an emulsifier and stabilizer for solutions. In addition, it is used to reduce inflammation on the skin. The unique lecithin will synergistically react with the dipotassium glycyrrhizinate to enhance the effect of the dipotassium glycyrrhizinate on encapsulation of the capsaicin. Additionally, the lecithin is used to reduce irritation that differs from inflammation. Inflamed skin is red and hot, irritated skin is itchy without necessarily being inflamed and red.

Esters of amino acids are next added to the formulation. Esters of amino acid usable in the scope of this invention are preferably menthyl and lauryl esters of amino acids. In the most preferred embodiment, the esters of amino acid are menthyl lauryl pidolate. This ester is comprised of menthyl as well as pidolic acid and lauric alcohol. This component has no odor. Typically, 0.1 - 1.0 wt. % is used in this compound in order to create the necessary analgesic effect. The active element in this component is menthol that acts as an analgesic. It is considered within the scope of the present invention to use enough menthyl lauryl pidolate to attain between 0.1 and 16 wt % menthol in the formulation.

The unique formulation is a topically (externally) applied formulation which has three simultaneous effects, analgesic, anesthetic and antipruritic effects, by (1) depressing cutaneous sensory receptors to relieve pain and (2) stimulating cutaneous sensory receptors using a topical counter irritant.

It is the combination of analgesic and anesthetic which make this invention unique.

Further, a light scattering compound is added to the formulation. Light scattering compounds can be any compound which has the ability to scatter light, such as by using particles having a diameter up to about 100 microns and more preferably between 30-60 microns.

Titanium dioxide is considered the best light scattering element for the present invention. Titanium dioxides usable within the scope of the present invention are preferably fine particle or pigmentary titanium dioxides available from Solaveil, of Durham, England. Any of the Solaviel TiO_2 products for cosmetic use can be used. All will reflects ultraviolet and provide broad UVB light protection, effectively scattering the light rays. In a preferred embodiment, the TiO_2 can provide a complete block of sunlight, and when mixed with the colloidal oatmeal, the light waves can be refracted and the skin protected from burning from the light.

Other than titanium dioxides, other components can be used for the light scattering purpose. For example, octyl dodecyl neopentanoate, can be used for light scattering. Bernell Chemical sells these compounds. Zinc oxide can be used as light scattering component, which also has the advantage of being anti-itch, or anti-pruritic effect.

Also, benzophenones, methoxycinnamate, para amino benzoic acid and combinations thereof can be used. It is also within the scope of the present invention, to add component onto the surface of the titanium dioxide to further enhance the effect of the titanium dioxide. In particular, aluminum stearate and aluminum oxide can be additionally used with the titanium dioxide for light scattering.

The titanium dioxide, with or without the aluminum are typically dispersed in caprylic/capric triglyceride, causing this component to contain approximately 50% by weight of solids.

It should be noted that other additives may be used in the present invention such as myristal myristate and other stearates for coagulation of the compound.

Xanthum gum can be added to the invention to provide a higher density compound, and act as a thickening agent. Other elements, such as licorice extract, glyceryl polymethacrylate and hydroxypropyl cellulose can be used in various formulations of the basic invention.

A suspension agent can be added to the formula of the present invention. Alkyl benzoate is considered usable within the scope of the present invention.

Deionized water is an excellent aqueous carrier for the present invention.

The present invention is fast acting and long acting due to the menthol present in the compositions. The uses of the invention are contemplated for post perpetic neuralgia, and scar conditions after surgery, such as for treating the scars from a mastectomy. Also, the present invention is considered usably for victims of neuropathy, such as diabetes with neuropathy.

In the method of the invention, a victim of pain or discomfort is treated by applying the above-described composition topically to the skin of the victim near an area affected by the pain

or discomfort. The types of pain or discomfort to which the invention may be applied include those discussed in the background of the invention. Generally speaking, the inventive composition, preferably in ointment or cream form, is applied to the selected area, such as a joint, and rubbed in. The amount applied is not critical. Generally, it should be applied in an amount that is sufficient to wet the area of application. Usually, the amount used will be in the range of from about 0.3 to about 3 ccs.

For the treatment of pruritus or itching, the application of the composition can be repeated as required to control the discomfort. When the preferred composition of the invention is applied, it provides near immediate relief from the itching caused by poison ivy or hemorrhoids, without a burning sensation. The relief lasts for several hours. It is surprising that a capsaicin-based composition would be useful for the treatment of such discomfort. To enhance the antipruritic effect, additional compounds can be added to the formulation. These components can be methyl sulphonyl methane, sodium bicarbonate, calamine, allantoin, kaolin, and combinations thereof.

For best results in the treatment of arthritis, the treatment should be repeated several times per day, such as in the range of 2 to 8 times per day, preferably 3-5 times per day, and continued for several days. Surprisingly, most patients do not experience the burning discomfort heretofore known as a very common side effect of topical capsaicin application.

It is contemplated to be within the scope of the present invention to use this formulation for a gel, a cream, an opaque cream, a spray using propellants, such as butyl propellants, and a liquid or lotion, such as a roll on.

It is even contemplated that the present invention could be used as a patch for treatment as well. Propellant for the spray on composition contemplated as usable herein can be selected from the group butane, propane, isobutane, and combinations thereof. A foam version of the formulation, additionally using a propellant and a surfactant is considered within the scope of the present invention. A preferred surfactant is a member of the group of amine oxides. The most preferred surfactant is alkyl dimethyl amine oxide.

The forgoing is a description of the composition and method of use of three embodiments of the invention. The scope of the invention is considered to include the described embodiment together with others obvious to those skilled in the art.

EXAMPLE 1 - *CREAM COMPOSITION*

The resulting cream composition made in accordance with one embodiment of the invention contains the following ingredients.

Ingredient	wt.%
Deionized water	48.29
Propylene glycol	5.00
Triethanolamine hydrochloride	0.40
Edetate disodium	0.02
Methyl paraben	0.30
Propyl paraben	0.10
Lavender extract	2.00
Bergamot extract	1.00
Capsicum frutescens	4.03
Xanthum gum	0.30
Histamine dihydrochloride	0.025
Hypericum perforatum extracts	1.00
Arnica montana extract	1.00
Aloe barbadensis gel	1.00
Myristal myristate	2.00
Alkyl benzoate	12.00
Colloidal oatmeal	3.50
Dipotassium glycyrrhizinate	1.00
Hydrogenated lecithin	1.00
Stearates	4.40
Dimethicone	1.00
Other preservatives	1.50
Menthyl lauryl pidolate	4.03
Titanium dioxide	3.00
Citric acid.	Q.S.

EXAMPLE 2 – GEL COMPOSITION

The resulting gel composition made in accordance with one embodiment of the invention contains the following ingredients.

Ingredient	wt.%
Deionized water	48.29
Propylene glycol	5.00
Triethanolamine	0.40
Edetate disodium	0.02
Methyl paraben	0.30
Propyl paraben	0.10
Lavender extract	2.00
Bergamot extract	1.00
Capsicum frutescens	4.03
Xanthum gum	0.30
Histamine dihydrochloride	0.025
Hypericum perforatum extracts	1.00
Arnica montana extract	1.00
Aloe barbadensis gel	1.00
Myristal myristate	2.00
Oat extract	3.50
Licorice extract	2.00
Glyceryl polymethacrylate	5.00
Hydroxypropylcellulose	5.00
Other preservatives	1.50
Menthyl lauryl pidolate	4.03
Benzophenone	3.00
Methoxyl cinnamate	1.00
Citric acid	Q.S.

EXAMPLE 3 - ROLL ON/LOTION COMPOSITION

The resulting roll on/lotion composition made in accordance with one embodiment of the invention contains the following ingredients.

Ingredient	wt.%
Deionized water	60.00
Propylene glycol	5.00
Triethanolamine	0.40
Edetate disodium	0.02
Methyl paraben	0.30
Propyl paraben	0.10
Lavender extract	2.00
Bergamot extract	1.00
Capsicum frutescens	4.03
Xanthum gum	0.30
Histamine dihydrochloride	0.025
Hypericum perforatum extracts	1.00
Arnica montana extract	1.00
Aloe barbadensis gel	1.00
Alkyl benzoate	11.00
Colloidal oatmeal	3.00
Dipotassium glycyrrhizinate	1.00
Hydrogenated lecithin	1.00
Stearates	2.00
Other preservatives	1.50
Menthyl lauryl pidolate	4.03
Cyclomethicone	5.00
Titanium dioxide	3.00
Citric acid	Q.S.

EXAMPLE 4 - COMPOSITION

The resulting composition made in accordance with one embodiment of the invention contains the following ingredients.

Ingredient	wt.%
Propyl paraben	0.10
Methyl paraben	0.20
Xanthum gum	0.35
Gellan gum	0.25
Propylene glycol	5.00
Glycerin	1.00
Panthenol	1.00
Arnica montana	2.00
Benzoic acid and alkyl esters (i.e. alkylbenzoate)	6.00
Benzyl alcohol	0.50
Methylsulfonylmethane	0.50
Water	66.50
Histamine dihydrochloride	0.10
Aloe barbadensis gel	1.00
Lavender oil	1.50
Bergamot oil	0.75
Peppermint oil	0.10
Ginger oil	0.50
Birch extract	1.00
Horseradish extract	0.50
Yarrow extract	0.25
Capsicum extract	0.25
Rosemary extract	0.25
Magnesium chloride	0.50

EXAMPLE 5 – DAY TIME FORMULA

The resulting day time formula composition made in accordance with one embodiment of the invention contains the following ingredients.

Ingredient	ranges of wt. in mg or %
Caffeine	32.50 - 65.00
Ibuprofen	200.00
Boswellin	50.00 - 250.00
Glucosamine	250.00 - 1500.00
Chondroitin	50.00 - 500.00
Ginko bilboa	30.00 - 120.00
Ginseng	250.00 - 500.00
Methylsulfonylmethane	500.00 - 3000.00
Glycyrrhizinate	0.001 - 2.00%
Stevia	1.00 - 1000.00
Capsaicin	1.0 mcg - 1.0 gram

EXAMPLE 6 – NIGHT TIME FORMULA

The resulting night time formula composition made in accordance with one embodiment of the invention contains the following ingredients.

Ingredient	ranges of wt. in mg or %
Ibuprofen	200.00
Glucosamine	250.00 - 1500.00
Chondroitin	50.00 - 500.00
Boswellin	50.00 - 250.00
Glycyrrhizinate	0.001 - 2.00%
Stevia	1.00 - 1000.00
Melatonin	1.00 - 10.00
Kava Kava	50.00 - 1000.00
Valerian Root	50.00 - 400.00
Passion Flower	50.00 - 800.00
Hops	50.00 - 400.00
Diphenhydramine hydrochloride	5.00 - 50.00
Capsaicin	1.0 mcg - 1.0 gram

The following examples are illustrative of the capsaicin lotion of the present invention.

EXAMPLE 7: LOTION FORMULATION

Ingredient	wt.%
Deionized water	60.00
Propylene glycol	5.00
Triethanolamine	0.40
Edetate disodium	0.02
Methyl paraben	0.30
Propyl paraben	0.10
Lavender extract	2.00
Bergamot extract	1.00
Capsicum frutescens	4.03
Xanthum gum	0.30
Histamine dihydrochloride	0.025
Hypericum perforatum extracts	1.00
Arnica montana extract	1.00
Aloe barbadensis gel	1.00
Alkyl Benzoate	11.00
Colloidal oatmeal	3.00
Dipotassium glycyrrhizinate	1.00
Stearates and PEG's	2.00
Other preservatives, benzyl alcohol	1.50
Menthyl lauryl pidolate	4.03
Cyclomethicone	5.00
Titanium dioxide solution	3.00
citric acid	Q.S.
Myristal myristate	

EXAMPLE 8: LOTION FORMULATION

Ingredient	range wt.%
Capsaicin	0.01 - 0.125
Glycerol Monostearate	1.00 - 5.00
Polysorbate	1.00 - 5.00
Titanium Dioxide	5.00 - 15.00
Benzyl alcohol	5.00 - 14.00
Colloidal oatmeal	2.00 - 10.00
Lavender oil	0.50 - 2.00
Propylene glycol	1.00 - 2.00
Uniphen P-23	0.10 - 0.005
Arnica	0.50 - 1.00
Aloe	1.00 - 10.00
Histidine	0.00 - 0.025
Xanthum gum	0.0001-0.005
Water	balance

In the most preferred embodiment, the invention relates to a composition comprising: a topical carrier; a transdermal component selected from the group comprising peppermint extract, ester, ginger extract, horseradish extract, yarrow extract, chamomile extract, rosemary extract, methylsulfonylmethane, benzyl alcohol, benzoic acid and combinations thereof; a capsicum extract; an encapsulation agent selected from the group comprising gums and resins and their derivatives; a solubility agent; a viscosity adjusting agent; and an analgesic agent.

In the preferred embodiment, the viscosity adjusting agent is a member of the group comprising magnesium chloride, citric acid, sodium chloride, and combinations thereof, and the analgesic agent is selected from the group histamine dihydrochloride, glucasomine, white willow bark, ibuprofen, salicylamide, salicylic acid and salsalate and combinations thereof. The encapsulation agent is preferably selected from the group consisting of xanthum gum, gellan gum, arabica gum, acacia gum, gum tragacanth, guar gum, dammar resin, elemi resin, sandarac resin, polyvinyl acetate, polyester, amide, carboxymethyl cellulose, carboxymethyl hydroxyethyl cellulose, carboxypolymethylene and combinations thereof.

Additionally, the composition can further comprise a skin and tissue emollient. For example, panthenol, dexpanthenol, vitamin B complex factor, glycerin, glycerol, sodium hyaluronate, myristal myristate, propylene glycol, natural nut oils and combinations thereof. If an amide is used, it is preferable powdered nylon or powdered sulfonamide.

The most preferred topical carrier is selected from the group comprising: aqueous carriers, oil based carriers, fat based carriers, and fatty alcohol based carriers, water or combinations thereof.

The preferred ester is an alkyl ester.

For the preferred embodiment, the analgesic agent is a member of the group comprising histamine hydrochloride and methylnicotinate.

The preferred histamine is histamine hydrochloride is a dihydrochloride.

The analgesic agent has a weight percent in the range of about 0.025% up to about 0.1%.

The capsicum extract is in the range of 0.01 to 20.0 % by weight.

The composition can additionally comprise a light scattering element selected from the group: titanium dioxide, zinc oxide, and benzophenones, methoxy cinnamate, para amino benzoic acid, octyl, dodecyl, neopentanoate, aluminum stearate with titanium dioxide, aluminum oxide with titanium dioxide, and combinations thereof.

The invention can also comprise an anti-itch agent, which is a member of the group: methyl sulphonyl methane, sodium bicarbonate, calamine, allantoin, kaolin, and combinations thereof.

The invention also includes a. patch for treating arthritis and neurological pains consisting of an elastomeric adhesive unit on which is disposed a formulation comprising an effective amount to treat arthritis and neurological pains comprising: a topical carrier; a transdermal component selected from the group comprising peppermint extract, ester, ginger extract, horseradish extract, yarrow extract, chamomile extract, rosemary extract, methylsulfonylmethane, benzyl alcohol, benzoic acid and combinations thereof; a capsicum extract; an encapsulation agent selected from the group comprising gums and resins and their derivatives; a solubility agent; a viscosity adjusting agent; and an analgesic agent.

The invention also applies a gel comprising: topical carrier; a transdermal component selected from the group comprising peppermint extract, ester, ginger extract, horseradish extract, yarrow extract, chamomile extract, rosemary extract, methylsulfonylmethane, benzyl alcohol, benzoic acid and combinations thereof; a capsicum extract; an encapsulation agent selected from the group comprising gums and resins and their derivatives; a solubility agent; a viscosity adjusting agent; and an analgesic agent.

The invention includes a sunscreen comprising. a topical carrier; a transdermal component

selected from the group comprising peppermint extract, ester, ginger extract, horseradish extract, yarrow extract, chamomile extract, rosemary extract, methylsulfonylmethane, benzyl alcohol, benzoic acid and combinations thereof; a capsicum extract; an encapsulation agent selected from the group comprising gums and resins and their derivatives; a solubility agent; a viscosity adjusting agent; and an analgesic agent; and a light scattering element having a particle size up to 100 nm.

A cream for treating pruritis comprising a topical carrier; a transdermal component selected from the group comprising peppermint extract, ester, ginger extract, horseradish extract, yarrow extract, chamomile extract, rosemary extract, methylsulfonylmethane, benzyl alcohol, benzoic acid and combinations thereof; a capsicum extract; an encapsulation agent selected from the group comprising gums and resins and their derivatives; a solubility agent; a viscosity adjusting agent; and an analgesic agent.

Preferably, the transdermal component is used in amounts from about 0.01 to about to 33.0%, more preferably from about 0.5% to about 9.0%.

The invention also relates to a hemorrhoid cream comprising an effective amount to treat hemorrhoids comprising: a topical carrier; a transdermal component selected from the group comprising peppermint extract, ester, ginger extract, horseradish extract, yarrow extract, chamomile extract, rosemary extract, methylsulfonylmethane, benzyl alcohol, benzoic acid and combinations thereof; a capsicum extract; an encapsulation agent selected from the group comprising gums and resins and their derivatives; a solubility agent; a viscosity adjusting agent; and an analgesic agent.

The invention relates to a lotion comprising: a topical carrier; a transdermal component selected from the group comprising peppermint extract, ester, ginger extract, horseradish extract, yarrow extract, chamomile extract, rosemary extract, methylsulfonylmethane, benzyl alcohol, benzoic acid and combinations thereof; a capsicum extract; an encapsulation agent selected from the group comprising gums and resins and their derivatives; a solubility agent; a viscosity adjusting agent; an analgesic agent.; and an emulsifying agent. The emulsifying agent is preferably glyceryl monostearate and polysorbate.

The invention also relates to a spray on formulation comprising: a propellant; a transdermal component selected from the group comprising peppermint extract, ester, ginger extract, horseradish extract, yarrow extract, chamomile extract, rosemary extract, methylsulfonylmethane, benzyl alcohol, benzoic acid and combinations thereof; a capsicum extract; an encapsulation agent selected from the group comprising gums and resins and their derivatives; a solubility agent; a viscosity adjusting agent; and an analgesic agent.

The propellant can be a butane, propane, isobutane, and combinations thereof.

The invention also pertains to a foam formulation comprising: a surfactant comprising an amine oxides; a propellant; a transdermal component selected from the group comprising peppermint extract, ester, ginger extract, horseradish extract, yarrow extract, chamomile extract, rosemary extract, methylsulfonylmethane, benzyl alcohol, benzoic acid and combinations thereof; a capsicum extract; an encapsulation agent selected from the group comprising gums and resins and their derivatives; a solubility agent; a viscosity adjusting agent; and an analgesic agent. The most preferred surfactant is amine oxide is alkyl dimethyl amine oxide.

The invention also relates to a method for treating a victim of a discomfort comprising the step of applying a composition containing capsicum extract wherein said compositions further comprise a topical carrier, a transdermal component selected from the group comprising peppermint extract, ester, ginger extract, horseradish extract, yarrow extract, chamomile extract, rosemary extract, methylsulfonylmethane, benzyl alcohol, benzoic acid and combinations thereof, wherein the topical carrier comprises a member selected from the group comprising water, aqueous carriers, oil based carriers, fat based carriers, and fatty alcohol based carrier and combinations thereof, an encapsulation agent selected from the group comprising gums and resins and their derivatives, a solubility agent, a viscosity agent comprising a member of the group: magnesium chloride, citric acid, sodium chloride and combinations thereof, and an analgesic agent selected from the group: histamine dihydrochloride, glucasomine, white willow bark, ibuprofen, salicylamide, salicylic acid and salsalate and combinations thereof, wherein said analgesic reduces capsicum extract induced skin irritation topically to the skin of the victim near an area affected by the discomfort.

The inventive method also works for victims that suffer from the discomfort caused by arthritis, hemorrhoids and pruritus.

The invention also relates to a daytime ingestible pain-relieving composition for human use comprising: a capsicum extract; an colloidal oatmeal encapsulation agent; an analgesic agent selected from the group histamine dihydrochloride, glucasomine, white willow bark, ibuprofen, salicylamide, salicylic acid and salsalate and combinations thereof, a pain-relieving component; a stimulant; an endurance enhancer, a mental alertness component, a stomach buffering agent, and a joint support supplement.

The preferred pain reliever is ibuprofen, the preferred stimulant is caffeine the preferred joint support supplement is selected from the group comprising Boswellin, glucosamine, Chondroitin and methylsulfonylmethane. The preferred endurance enhancer is ginseng. The preferred mental alertness component is ginko biloba. The most preferred stomach-buffering agents are either stevia or glycyrrhizinate.

Finally, the invention also relates to a nighttime ingestable pain-relieving composition for human use comprising: a capsicum extract; a colloidal oatmeal encapsulation agent; an analgesic agent selected from the group histamine dihydrochloride, glucosamine, white willow bark, ibuprofen, salicylamide, salicylic acid and salsalate and combinations thereof; a pain-relieving component; a sleep agent; a joint support supplement, and stomach buffering agent.

For this embodiment, the pain-relieving component is ibuprofen, acetaminophen, salicylamide and combinations thereof The preferred sleep agent is melatonin, kava kava, valerian root, passion flower, hops and diphenhydramine hydrochloride and combinations thereof.. The joint support supplement boswellin, glucosamine, chondroitin or methylsulfonylmethane. The stomach buffering agent selected from the group stevia and glycyrrhizinate.

CLAIMS

What is claimed is:

1. A composition comprising:

a topical carrier;

a transdermal component selected from the group comprising peppermint extract, ester, ginger extract, horseradish extract, yarrow extract, chamomile extract, rosemary extract, methylsulfonylmethane, benzyl alcohol, benzoic acid and combinations thereof;

a capsicum extract;

an encapsulation agent selected from the group comprising gums and resins and their derivatives;

a solubility agent;

a viscosity adjusting agent, and

an analgesic agent.

2. The composition of claim 1, wherein the viscosity adjusting agent is a member of the group comprising magnesium chloride, citric acid, sodium chloride, and combinations thereof.

3. The composition of claim 1, wherein the analgesic agent is selected from the group. histamine dihydrochloride, glucosamine, white willow bark, ibuprofen, salicylamide, salicylic acid and salsalate and combinations thereof.

4. The composition of claim 1, wherein said encapsulation agent is selected from the group consisting of xanthum gum, gellan gum, arabica gum, acacia gum, gum tragacanth, guar gum, dammar resin, elemi resin, sandarac resin, polyvinyl acetate, polyester, amide, carboxymethyl cellulose, carboxymethyl hydroxyethyl cellulose, carboxypolymethylene and combinations thereof.

5. The composition of claim 1, further comprising a skin and tissue emollient.

6. The composition of claim 5, wherein the skin and tissue emollient is selected from the group panthenol, dexpanthenol, vitamin B complex factor, glycerin, glycerol, sodium hyaluronate, myristal myristate, propylene glycol, natural nut oils and combinations thereof.

7. The composition of claim 4, wherein said amide is selected from the group powdered nylon and powdered sulfonamide.

8. The composition of claim 1, wherein said topical carrier is selected from the group comprising: aqueous carriers, oil based carriers, fat based carriers, and fatty alcohol based carriers, water or combinations thereof.

9. The composition of claim 1, wherein said ester is an alkyl ester.

10. The composition of claim 1, wherein said analgesic agent is a member of the group comprising histamine hydrochloride and methylnicotinate.

11. The composition as in claim 10, wherein said histamine hydrochloride is a dihydrochloride.

12. The composition of claim 10, wherein said analgesic agent has a weight percent in the range of about 0.025% up to about 0.1%.

13. The composition of claim 1, wherein said capsicum extract is in the range of 0.01 to 20.0 % by weight.

14. The composition of claim 1, further comprising a light scattering element selected from the group: titanium dioxide, zinc oxide, and benzophenones, methoxy cinnamate, para amino benzoic acid, octyl, dodecyl, neopentanoate, aluminum stearate with titanium dioxide, aluminum oxide with titanium dioxide, and combinations thereof.

15. The composition of claim 1, further comprises an anti-itch agent which is a member of the group: methyl sulphonyl methane, sodium bicarbonate, calamine, allantoin, kaolin, and combinations thereof.

16. A patch for treating arthritis and neurological pains consisting of an elastomeric adhesive unit on which is disposed a formulation comprising an effective amount to treat arthritis and neurological pains comprising:

a topical carrier;

a transdermal component selected from the group comprising peppermint extract, ester, ginger extract, horseradish extract, yarrow extract, chamomile extract, rosemary extract, methylsulfonylmethane, benzyl alcohol, benzoic acid and combinations thereof;

a capsicum extract;

an encapsulation agent selected from the group comprising gums and resins and their derivatives;

a solubility agent;

a viscosity adjusting agent, and

an analgesic agent.

17. A gel comprising:

a topical carrier;

a transdermal component selected from the group comprising peppermint extract, ester, ginger extract, horseradish extract, yarrow extract, chamomile extract, rosemary extract, methylsulfonylmethane, benzyl alcohol, benzoic acid and combinations thereof;

a capsicum extract;

an encapsulation agent selected from the group comprising gums and resins and their derivatives;

a solubility agent;

a viscosity adjusting agent, and

an analgesic agent.

18. A sunscreen comprising:

a topical carrier;

a transdermal component selected from the group comprising peppermint extract, ester, ginger extract, horseradish extract, yarrow extract, chamomile extract, rosemary extract, methylsulfonylmethane, benzyl alcohol, benzoic acid and combinations thereof;

a capsicum extract;

an encapsulation agent selected from the group comprising gums and resins and their derivatives;

a solubility agent;

a viscosity adjusting agent; and

an analgesic agent, and

a light scattering element having a particle size up to 100 nm.

19. A cream for treating pruritus comprising:

a topical carrier;

a transdermal component selected from the group comprising peppermint extract, ester, ginger extract, horseradish extract, yarrow extract, chamomile extract, rosemary extract, methylsulfonylmethane, benzyl alcohol, benzoic acid and combinations thereof;

a capsicum extract;

an encapsulation agent selected from the group comprising gums and resins and their derivatives;

a solubility agent;

a viscosity adjusting agent, and

an analgesic agent.

20. The cream of claim 19, wherein said transdermal component is used in amounts ranging from about 0.01 to about to 33.0%.

21 The cream of claim 19, further wherein said transdermal component is used in amounts ranging from about 0.5% to about 9.0%.

22. A hemorrhoid cream comprising an effective amount to treat hemorrhoids comprising:

a topical carrier;

a transdermal component selected from the group comprising peppermint extract, ester, ginger extract, horseradish extract, yarrow extract, chamomile extract, rosemary extract, methylsulfonylmethane, benzyl alcohol, benzoic acid and combinations thereof;

a capsicum extract;

an encapsulation agent selected from the group comprising gums and resins and their derivatives;

a solubility agent;

a viscosity adjusting agent, and

an analgesic agent.

23. A lotion comprising:

a topical carrier;

a transdermal component selected from the group comprising peppermint extract, ester, ginger extract, horseradish extract, yarrow extract, chamomile extract, rosemary extract, methylsulfonylmethane, benzyl alcohol, benzoic acid and combinations thereof;

a capsicum extract;

an encapsulation agent selected from the group comprising gums and resins and their derivatives;

a solubility agent;

a viscosity adjusting agent;

an analgesic agent, and

an emulsifying agent.

24. The lotion of claim 23, wherein said emulsifying agent is selected from the group comprising glyceryl monostearate and polysorbate.

25. A spray on formulation comprising:

a propellant;

a transdermal component selected from the group comprising peppermint extract, ester, ginger extract, horseradish extract, yarrow extract, chamomile extract, rosemary extract, methylsulfonylmethane, benzyl alcohol, benzoic acid and combinations thereof;

a capsicum extract;

an encapsulation agent selected from the group comprising gums and resins and their derivatives;

a solubility agent;

a viscosity adjusting agent, and

an analgesic agent.

26. The spray of claim 25, wherein the propellant is selected from the group: butane, propane, isobutane, and combinations thereof.

27. A foam formulation comprising:

a surfactant comprising an amine oxides;

a propellant;

a transdermal component selected from the group comprising peppermint extract, ester, ginger extract, horseradish extract, yarrow extract, chamomile extract, rosemary extract, methylsulfonylmethane, benzyl alcohol, benzoic acid and combinations thereof;

a capsicum extract;

an encapsulation agent selected from the group comprising gums and resins and their derivatives;

a solubility agent;

a viscosity adjusting agent, and

an analgesic agent.

28. The foam of claim 27, wherein said surfactant is amine oxide is alkyl dimethyl amine oxide.

29. A method for treating a victim of a discomfort comprising the step of applying a composition containing capsicum extract wherein said compositions further comprise a topical carrier, a transdermal component selected from the group comprising peppermint extract, ester, ginger extract, horseradish extract, yarrow extract, chamomile extract, rosemary extract, methylsulfonylmethane, benzyl alcohol, benzoic acid and combinations thereof, wherein the topical carrier comprises a member selected from the group comprising water, aqueous carriers, oil based carriers, fat based carriers, and fatty alcohol based carrier and combinations thereof, an encapsulation agent selected from the group comprising gums and resins and their derivatives, a solubility agent, a viscosity agent comprising a member of the group: magnesium chloride, citric acid, sodium chloride and combinations thereof, and an analgesic agent selected from the group: histamine dihydrochloride, glucosamine, white willow bark, ibuprofen, salicylamide, salicylic acid and salsalate and combinations thereof, wherein said analgesic reduces capsicum extract induced skin irritation topically to the skin of the victim near an area affected by the discomfort.

30. The method as in claim 29, wherein the victim suffers from the discomfort caused by arthritis.

31. The method as in claim 29, wherein the victim suffers from the discomfort caused by hemorrhoids.

32. The method as in claim 29, wherein the victim suffers from the discomfort caused by pruritis.

33. A daytime ingestible pain-relieving composition for human use comprising:

a capsicum extract;

an colloidal oatmeal encapsulation agent ;

an analgesic agent selected from the group histamine dihydrochloride, glucosamine, white willow bark, ibuprofen, salicylamide, salicylic acid and salsalate and combinations thereof,

a pain-relieving component;

a stimulant;

an endurance enhancer,

a mental alertness component,

a stomach buffering agent, and

a joint support supplement.

34. The composition of claim 33, wherein said pain reliever is ibuprofen.

35. The composition of claim 33, wherein said stimulant is caffeine.

36. The composition of claim 33, wherein said joint support supplement is selected from the group comprising boswellin, glucosamine, chondroitin and methylsulfonylmethane.

37. The composition of claim 33, wherein said endurance enhancer is ginseng.

38. The composition of claim 33, wherein said mental alertness component is ginko biloba.

39. The composition of claim 33, wherein said stomach buffering agent is selected from the group stevia and glycyrrhizinate.

40. A nighttime ingestable pain-relieving composition for human use comprising:

a capsicum extract;

a colloidal oatmeal encapsulation agent;

an analgesic agent selected from the group histamine dihydrochloride, glucosamine, white willow bark, ibuprofen, salicylamide, salicylic acid and salsalate and combinations thereof;

a pain-relieving component;

a sleep agent;

a joint support supplement, and

stomach buffering agent.

41. The composition of claim 40, wherein said pain-relieving component is ibuprofen, acetaminophen, salicylamide and combinations thereof.

42. The composition of claim 40, wherein said sleep agent is melatonin, kava kava, valerian root, passion flower, hops and diphenhydramine hydrochloride and combinations thereof.

43. The composition of claim 40, wherein said joint support supplement is selected from the group comprising boswellin, glucosamine, chondroitin and methylsulfonylmethane.

44. The composition of claim 40, further comprising a stomach buffering agent selected from the group stevia and glycyrrhizinate.

45. A lotion comprising:

capsaicin;

an encapsulation agent selected from the group comprising colloidal oatmeal, hydrogenated lecithin, dipotassium glycyrrhizinate and combinations thereof;

a light scattering element having a particle size up to 100 nm;

a coagulating agent selected from the group consisting of xanthum gum, myristal myristate, polyethylene glycol and mixtures thereof;

a transdermal activator selected from the group consisting of lavender oil, bergaptene-free bergamot oil and mixtures thereof;

an ester of amino acid;

an analgesic, and

a topical carrier.

46. The lotion in accordance with claim 45, wherein said analgesic is selected a histidine.

47. The lotion in accordance with claim 46, wherein said histidine is selected from the group consisting of L-histidines, histamine dihydrocholoride, DL-histidine, D-histidine hydrochloride monohydrate, L-histidine hydrochloride monohydrate, L-histidine methyl ester dihydrochloride, L-histidinol dihydrochloride, histamine phosphate.

48. The lotion in accordance with claim 45, further comprising hypericum perforatum, arnica montana, capric acid and at least one preservative.

49. The lotion in accordance with claim 45, wherein said topical carrier is selected from the group consisting of aqueous carriers, oil based carriers, fat based carriers, and fatty alcohol based carriers, and combinations thereof.

50. The lotion in accordance with claim 45, wherein said capsaicin is selected from the group consisting of nordihydrocapasaicin, capsaicin, dihydrocapsaicin, homocapsaicin, and combinations thereof.

51. The lotion in accordance with claim 45, wherein said capsaicin is in the range of from about 0.125 to about 1.0 %/wt.

52. The lotion in accordance with claim 45, wherein said capsaicin is in the range of from about 0.025 to about 20.0 %/wt.

53. The lotion in accordance with claim 45, wherein said capsaicin is in the range of from about 0.025 to about 1.0 %/wt.

54. The lotion in accordance with claim 52, wherein said capsaicin is in the range of from about 0.025 to about 0.25 %/wt.

55. The lotion in accordance with claim 45, wherein said esters of amino acids are selected from the group consisting of menthyl and lauryl esters of amino acids and combinations thereof.

56. The lotion in accordance with claim 55, wherein said esters of amino acid is in the range of from about 0.10 to about 1.0 %/wt.

57. The lotion in accordance with claim 55, wherein said esters of amino acid is menthyl in an amount sufficient to achieve from about 0.1 to about 16 %/wt. menthol in the formulation.

58. The lotion in accordance with claim 57, wherein said ester of amino acid is menthyl lauryl pidolate.

59. The lotion in accordance with claim 55, wherein said light scattering element has a particle size of between about 30 microns and about 60 microns in diameter.

60. The lotion in accordance with claim 55, wherein said light scattering element is selected from the group consisting of titanium dioxide, zinc oxide, and benzophenones, methoxy cinnamate, para amino benzoic acid, octyl, dodecyl, neopentanoate, aluminum stearate with titanium dioxide, aluminum oxide with titanium dioxide, and combinations thereof.

61. The lotion in accordance with claim 55, further comprising an additional anti-itch agent which is a member of the group: methyl sulphonyl methane, sodium bicarbonate, calamine, allantoin, kaolin, and combinations thereof.

62. The lotion in accordance with claim 57, wherein said histidine is histamine dihydrochloride.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/26027

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61K 31/275
US CL : 514/627
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 514/627

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,812,446 A (BRAND) 14 March 1989(14/03/89), see entire document, especially abstract, column 3 through column 14, examples 15.	1-62
Y	US 4,681,897 A (BRAND) 21 July 1987 (21/07/87), see entire document, especially abstract, column 3 through 8, examples 1-15.	1-62

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

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